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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,678	12/08/2003	Benjamin Oshlack	02755/0205241-US0	4265
7278	7590	10/20/2006	EXAMINER	
DARBY & DARBY P.C.			FITZGERALD, MARC C	
P. O. BOX 5257			ART UNIT	PAPER NUMBER
NEW YORK, NY 10150-5257			1615	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/731,678

Applicant(s)

OSHLACK ET AL.

Examiner

Marc C. Fitzgerald

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 80-142 is/are pending in the application.
- 4a) Of the above claim(s) 107-142 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 80-106 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Status of Application**

The Examiner thanks the Applicants for their timely reply filed on 20 July 2006, in the matter of 10/731,678. A response to the remarks and amendments are herein presented under C.F.R. § 1.113. Claims 80-142 are pending.

### ***Newly Submitted Claims***

Please note that the newly submitted claims 107-142 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the invention designated in claims 80-142 contains additional limitations, i.e., a unit dose of an effective amount of oxymorphone comprising a plurality of substrates comprising a hydrophilic polymer, a hydrophobic polymer, a digestible long chain hydrocarbon, a polyalkylene glycol, or a mixture thereof. The additional limitations suggests a structurally different invention than originally claimed and will require separate searching of the art, particularly if a substrate other than a hydrophilic polymer is selected from the Markush group.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 107-142 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Response to Remarks***

***Obvious Type Double Patenting Rejection***

1. Claims 80-106 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17, 19-26, and 28-66 of U.S. Patent No. 5,965,161 in view of *Remington: The Science and Practice of Pharmacy, Nineteenth Ed.*
2. Applicant argues the obvious-type double patenting rejection is improper and should be withdrawn on the basis that the rejection discusses only the '161 patent specification without ever mentioning what is claimed by that patent.
3. Applicant's arguments on pp. 12-14 in the Remarks received on 20 July 2006 have been considered but are not found to be persuasive. The claims at issue are clearly stated in the rejection as being claims 1-17, 19-26, and 28-66. Claims 12 and 17 state a capsule comprising the required ingredients. The reference to the specific citations in the specification are included to magnify the exemplification of the patent. Hence the rejection is over the claims not the specification. The obvious-type double patenting rejection is maintained.

***Claims Rejection(s) – 35 U.S.C. § 103***

4. Claims 80-106 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,472,712 to Oshlack et al. ('712) in view of U.S. Patent No. 4,464,378 to Hussain ('378).
5. Applicant argues that the 103(a) Rejection is improper because it is only available as 102(e) art.
6. For a detailed discussion of proper 103 art, the Applicant is directed to the MPEP § 706.02 (j) and 2141-2144 wherein it states, *"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made."*
7. Applicant further argues that the 103(a) Rejection should be withdrawn because '378 describes a nasal composition whereas the instant composition is being administered orally and therefore the art is not analogous.

8. The prior art references of '712 and '378 are related because they describe pharmaceutical compositions of opioid analgesics administered at pharmaceutically acceptable amount. US '712 teaches the opioid analgesic and process of making the analgesic composition with all the all the required limitations of the instant application; except it does not recite oxymorphone as the opioid analgesic. In stead it teaches hydroxymorphone. US '378 teaches a controlled formulation for the administration of oxymorphone and hydroxymorphone. US '378 teaches that the two analgesics are used equivalently. Thus as detailed in the rejection of record mailed on 1/20/06, the combined teachings would suggest to one of ordinary skill in the art that one could modify the teachings of US '712 with those of '378 to obtain the embodiment of the instant claims. The fact that US '378 describes a nasal route of administration versus an oral route does not obviate the rejection. The instant claims are to a composition not method of administration. The applicant is directed to *In re Casey*, 152 USPQ 2135 (CCPA 1967) and *In re Otto*, 138 USPQ 458, 459 (CCPA 1963) wherein a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Furthermore, the Figure in '378 clearly indicates that the dosage form can be administered via oral, nasal, and intravenous routes. The 103 Rejection is maintained.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

***Conclusion***

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Pertinent Art(s)***

U.S. Patent 4,668,685 is made of record because it describes a sustained-release dosage form of a prodrug of oxymorphone containing a hydrophilic polymer, a hydrophobic polymer, a digestible long chain hydrocarbon, or polyethylene glycol.

U.S. Patent 5,099,030 is made of record because it teaches sustained release tablet and capsule and method of making comprising an opioid analgesic, ethyl cellulose, a binder and diluent.

***Correspondences***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc C. Fitzgerald whose telephone number is (571) 272-8510. The examiner can normally be reached between 9:30 AM - 6:30 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marc C. Fitzgerald  
Art Unit -1615

11 October 2006

  
MICHAEL P. WOODWARD  
SUPERVISORY PATENT EXAMINER  
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